

**EXHIBIT D**  
**OFFICE ACTION (11/27/2000)**

**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, DC 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/077,719	06/08/98	COTTON	H 1103326-502
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007470  
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HM22/1127

EXAMINER

FAN, J

ART UNIT

PAPER NUMBER

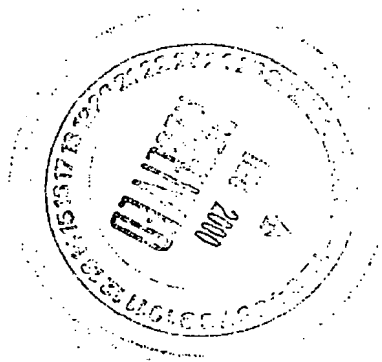
1625

DATE MAILED:

11/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



2/27/01  
5/27/01

**Office Action Summary**

Application No.

09/077,719

Applicant(s)

Cotton et al.

Examiner

Jane Fan

Group Art Unit

1625

☒ Responsive to communication(s) filed on Oct 30, 2000☐ This action is FINAL.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**☒ Claim(s) 1-14 and 16-18 is/are pending in the application.Of the above, claim(s) 5-13 and 18 is/are withdrawn from consideration.☐ Claim(s) \_\_\_\_\_ is/are allowed.☒ Claim(s) 1-4, 14, 16, and 17 is/are rejected.☐ Claim(s) \_\_\_\_\_ is/are objected to.☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☒ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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This application is filed under 35 USC 371. Claims 1-18 are pending.

The pending claims are drawn to the following groups of inventions:

- I. Claims 1-3, 14-17, drawn to the magnesium salt of S-omeprazole trihydrate, its composition and method of use, classified in classes 514, 546, subclasses various.
- II. Claim 4, drawn to one method of making the compound of group I, classified in class 546, subclasses various.
- III. Claims 5-9, drawn to another method of making the compound of group I, classified in class 546, subclasses various.
- IV. Claims 10-12, drawn to a process of making potassium salt of S-omeprazole, classified in class 546, subclass various.
- V. Claim 13, drawn to potassium salt of S-omeprazole, classified in class 546, subclass various.
- VI. Claim 18, drawn to a composition of the magnesium salt of S-omeprazole trihydrate and another therapeutic agent.

Applicants are required under 37 CFR 1.499 to elect one product between group I and V and one specific process between II and III if group I is elected which has been adapted specifically for making the elected compounds for prosecution.

During a telephone conversation with Mr. Genova on November 13, 2000 a provisional election was made with traverse to prosecute the invention of groups I-II, claims 1-4, 14, 16-17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5-

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13, 18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 14, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over .

- ✓ 1. Pat' 4,738,974, example 5 ( dihydrate form ).
- ✓ 2. Pat' 5,693,818, examples 3-7.
- 3. WO 95/01977, page 3, lines 30-31 ( for claim 4, see page 5, lines 7-8)
- ✓ 4. Pat' 5,690,960, examples 2, 4.
- ✓ 5. Kallstrom et al. pat' 5,900,424.

Optionally in view of Evans or Japan Chemical Society, Experimental chemical Seminar Vol. 18, 1958 pages 505.

In establishing prima facie obviousness, the following criteria are considered:

- (a) All references (except reference 1 ) disclose some form of magnesium salt of omeprazole without clearly specify water content. (MPEP 2141.01).
- (b). The difference between the claims and the references' disclosure is that the claimed compound is S-form and trihydrate (MPEP 2141.02).

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(c). Since the art references( except reference 1 ) are silent regarding the water content of the salt form, one having ordinary skilled in the art would have expected the art compound in the process of preparing inherently has water molecule attached ( especially WO 95/01977, page 5, lines 7-8, example 1, line 13) (MPEP 2143.01-02).

It is recognized in the art that organic solid material may include guest molecules to form crystals. However, the guest inclusion is mechanical in nature ( see Evans p. 396), thus the instant claims are drawn to alternative form of a known compound. The alternative form is the innate nature for such a compound. Furhtermore, the Japanese reference teaches that spontaneous resolution occurs in recrytlization. It is expected that if the crystalization solvet is water, then optical pure hydrate would result.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 14, 16-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 5,900,424, 4,738,974,5,714,504 optionally in view of Evans or Japan Chemical Society, Experimental

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chemical Seminar Vol. 18, 1958 pages 505. Although the conflicting claims are not identical, they are not patentably distinct from each other because alternative form of a known compound is obvious.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Fan whose telephone number is (703) 308-4705.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

JTF November 27, 2000

  
JANE FAN  
PRIMARY EXAMINER  
GROUP 1200

<b>Notice of References Cited</b>				Application No. <b>09/077,719</b>		Applicant(s) <b>Cotton et al.</b>	
				Examiner <b>Jane Fan</b>		Group Art Unit <b>1625</b>	
<b>U.S. PATENT DOCUMENTS</b>							
		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	
*	A	4,738,974	Apr. 1988	Brandstrom	514	338	
*	B	5,714,504	Feb. 1998	Lindberg et al.	514	338	
*	C	5,693,818	Dec. 1997	Vion Unge	514	338	
*	D	5,690,960	Nov. 1997	Bengtsson et al.	514	338	
*	E	59,004,274	5/1999	Kallstrom et al.	514	338	
	F						
	G						
	H						
	I						
	J						
	K						
	L						
	M						
<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS
*	N	WO 95/01977	1/1995	Europe	Kallstrom et al.	---	---
	O						
	P						
	Q						
	R						
	S						
	T						
<b>NON-PATENT DOCUMENTS</b>							
		DOCUMENT (Including Author, Title, Source, and Pertinent Pages)					DATE
	u	Japanese chemical society, Experimental Chemical Seminar. Vol. 18. p.55 (translation)					1958
	v	An Introduction to Crystal Chemistry by EVANS Cambridge At the Univ. Press					1964
	w						
	x						